Complete Summary

GUIDELINE TITLE

Gestational diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

Gestational diabetes mellitus. Diabetes Care 2004 Jan; 27(Suppl 1): S88-90. [5 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
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BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
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CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Gestational diabetes mellitus

GUIDELINE CATEGORY

Diagnosis Management Risk Assessment Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Dietitians Nurses Physicians

GUIDELINE OBJECTIVE(S)

To present recommendations for the detection, diagnosis, and management of gestational diabetes mellitus

TARGET POPULATION

- Pregnant women at risk of developing gestational diabetes mellitus
- Pregnant women with gestational diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment and Diagnosis

- 1. Assessment of risk factors for gestational diabetes mellitus at the first prenatal visit
- 2. Plasma or serum glucose testing (fasting or casual)
- 3. One-step approach: diagnostic oral glucose tolerance test without prior plasma or serum glucose screening
- 4. Two-step approach: Initial screening by measuring the plasma or serum glucose concentration 1 hour after a 50-g oral glucose load (glucose challenge test) followed by a diagnostic oral glucose tolerance test on that subset of women exceeding the glucose threshold value on the glucose challenge test

Management/Treatment

1. Monitoring

- Maternal metabolic surveillance directed at detecting hyperglycemia severe enough to increase risks to the fetus (daily self-monitoring of blood glucose, 1 or 2 hour, postprandial monitoring of whole blood glucose or plasma glucose, fasting whole blood or plasma glucose)
- Urine ketone monitoring, as indicated, to detect insufficient caloric or carbohydrate intake in women treated with calorie restriction
- Blood pressure and urine protein monitoring to detect hypertensive disorders
- Increased surveillance for pregnancies at risk for fetal demise
- Assessment for asymmetric fetal growth by ultrasonography

Note: Urine glucose monitoring is considered, but not recommended.

2. Nutritional counseling

- Individualization of medical nutrition therapy depending on maternal weight and height
- Noncaloric sweeteners in moderation
- Calorie or carbohydrate restriction, as indicated
- 3. Insulin therapy: Human insulin with doses and timing of insulin regime guided by self-monitoring of blood glucose
- 4. Measurement of the fetal abdominal circumference early in the third trimester

- 5. Physical exercise to lower maternal glucose concentrations
- 6. Delivery during the 38th week, as indicated
- 7. Encouragement of maternal breast-feeding
- 8. Follow-up
 - Reclassification of maternal glycemic status 6 weeks after delivery
 - Reassessment of glycemia (frequency determined by postpartum glucose levels)
 - As appropriate, medical nutrition therapy and exercise program
 - Patient education (maintenance of normal body weight, avoidance of medications that worsen insulin resistance, when to seek medical attention, family planning, oral contraceptives)
 - Assessment of offspring of women with gestational diabetes mellitus for the development of obesity and/or abnormalities of glucose tolerance

Note: Glyburide is considered for treatment but not recommended.

MAJOR OUTCOMES CONSIDERED

- Maternal glucose levels
- Maternal morbidity and complications of pregnancy
- Fetal morbidity and mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Detection and Diagnosis

Risk assessment for gestational diabetes mellitus should be undertaken at the first prenatal visit. Women with clinical characteristics consistent with a high risk of gestational diabetes mellitus (marked obesity, personal history of gestational diabetes mellitus, glycosuria, or a strong family history of diabetes) should undergo glucose testing (see below) as soon as feasible. If they are found not to have gestational diabetes mellitus at that initial screening, they should be retested between 24 and 28 weeks of gestation. Women of average risk should have testing undertaken at 24 to 28 weeks of gestation. Low-risk status requires no glucose testing, but this category is limited to those women meeting all of the following characteristics:

- Age < 25 years
- Weight normal before pregnancy

- Member of an ethnic group with a low prevalence of gestational diabetes mellitus
- No known diabetes in first-degree relatives
- No history of abnormal glucose tolerance
- No history of poor obstetric outcome

A fasting plasma glucose level >126 mg/dL (7.0 mmol/L) or a casual plasma glucose >200 mg/dL (11.1 mmol/L) meets the threshold for the diagnosis of diabetes, if confirmed on a subsequent day, and precludes the need for any glucose challenge. In the absence of this degree of hyperglycemia, evaluation for gestational diabetes mellitus in women with average or high-risk characteristics should follow one of two approaches:

One-step approach: Perform a diagnostic oral glucose tolerance test (OGTT) without prior plasma or serum glucose screening. The one-step approach may be cost-effective in high-risk patients or populations (e.g., some Native-American groups).

Two-step approach: Perform an initial screening by measuring the plasma or serum glucose concentration 1 hour after a 50-g oral glucose load (glucose challenge test [GCT]) and perform a diagnostic oral glucose tolerance test on that subset of women exceeding the glucose threshold value on the glucose challenge test. When the two-step approach is employed, a glucose threshold value >140 mg/dL (7.8 mmol/L) identifies approximately 80% of women with gestational diabetes mellitus, and the yield is further increased to 90% by using a cutoff of >130 mg/dL (7.2 mmol/L).

With either approach, the diagnosis of gestational diabetes mellitus is based on an oral glucose tolerance test. Diagnostic criteria for the 100-g oral glucose tolerance test are shown in Table 1, below. Alternatively, the diagnosis can be made using a 75-g glucose load and the glucose threshold values listed for fasting, 1 hour, and 2 hours (Table 2, below); however, this test is not as well validated for detection of at-risk infants or mothers as the 100-g oral glucose tolerance test.

Table 1. Diagnosis of gestational diabetes mellitus with a 100-g oral glucose load

	mg/dL	mmol/L
Fasting	95	5.3
1-h	180	10.0
2-h	155	8.6
3-h	140	7.8

Two or more of the venous plasma concentrations must be met or exceeded for a positive diagnosis. The test should be done in the morning after an overnight fast

of between 8 and 14 h and after at least 3 days of unrestricted diet (\geq 150 g carbohydrate per day) and unlimited physical activity. The subject should remain seated and should not smoke throughout the test.

Table 2. Diagnosis of gestational diabetes mellitus with a 75-g oral glucose load

	mg/dL	mmol/L
Fasting	95	5.3
1-h	180	10.0
2-h	155	8.6

Two or more of the venous plasma concentrations must be met or exceeded for a positive diagnosis. The test should be done in the morning after an overnight fast of between 8 and 14 h and after at least 3 days of unrestricted diet (\geq 150 g carbohydrate per day) and unlimited physical activity. The subject should remain seated and should not smoke throughout the test.

Information on obstetric and perinatal considerations can be found in the original guideline document.

Monitoring

- Maternal metabolic surveillance should be directed at detecting hyperglycemia severe enough to increase risks to the fetus. Daily self-monitoring of blood glucose (SMBG) appears to be superior to intermittent office monitoring of plasma glucose. For women treated with insulin, limited evidence indicates that postprandial monitoring is superior to preprandial monitoring. However, the success of either approach depends on the glycemic targets that are set and achieved.
- Urine glucose monitoring is not useful in gestational diabetes mellitus. Urine ketone monitoring may be useful in detecting insufficient caloric or carbohydrate intake in women treated with calorie restriction.
- Maternal surveillance should include blood pressure and urine protein monitoring to detect hypertensive disorders.
- Increased surveillance for pregnancies at risk for fetal demise is appropriate, particularly when fasting glucose levels exceed 105 mg/dL (5.8 mmol/L) or pregnancy progresses past term. The initiation, frequency, and specific techniques used to assess fetal well-being will depend on the cumulative risk the fetus bears from gestational diabetes mellitus and any other medical/obstetric conditions present.
- Assessment for asymmetric fetal growth by ultrasonography, particularly in early third trimester, may aid in identifying fetuses that can benefit from maternal insulin therapy (see below).

Management

- All women with gestational diabetes mellitus should receive nutritional
 counseling, by a registered dietitian when possible, consistent with the
 recommendations by the American Diabetes Association. Individualization of
 medical nutrition therapy depending on maternal weight and height is
 recommended. Medical nutrition therapy should include the provision of
 adequate calories and nutrients to meet the needs of pregnancy and should
 be consistent with the maternal blood glucose goals that have been
 established. Noncaloric sweeteners may be used in moderation.
- For obese women (body mass index >30), a 30 to 33% calorie restriction (to ~25 kcal/kg actual weight per day) has been shown to reduce hyperglycemia and plasma triglycerides with no increase in ketonuria (Franz et al., 1994). Restriction of carbohydrates to 35 to 40% of calories has been shown to decrease maternal glucose levels and improve maternal and fetal outcomes (Major et al., 1998).
- Insulin is the pharmacologic therapy that has most consistently been shown
 to reduce fetal morbidities when added to medical nutrition therapy (MNT).
 Selection of pregnancies for insulin therapy can be based on measures of
 maternal glycemia with or without assessment of fetal growth characteristics.
 When maternal glucose levels are used, insulin therapy is recommended when
 medical nutrition therapy fails to maintain self-monitored glucose at the
 following levels:

Fasting plasma glucose \leq 105 mg/dL (5.8 mmol/L)

or

1-hour postprandial plasma glucose \leq 155 mg/dL (8.6 mmol/L)

or

2-hour postprandial plasma glucose \leq 130 mg/dL (7.2 mmol/L)

- Measurement of the fetal abdominal circumference early in the third trimester can identify a large subset of infants with no excess risk of macrosomia in the absence of maternal insulin therapy. This approach has been tested primarily in pregnancies with maternal fasting serum glucose levels less than 105 mg/dL (5.8 mmol/L).
- Human insulin should be used when insulin is prescribed, and self-monitoring of blood glucose should guide the doses and timing of the insulin regimen.
- Programs of moderate physical exercise have been shown to lower maternal
 glucose concentrations in women with gestational diabetes mellitus. Although
 the impact of exercise on neonatal complications awaits rigorous clinical trials,
 the beneficial glucose-lowering effects warrant a recommendation that women
 without medical or obstetrical contraindications be encouraged to start or
 continue a program of moderate exercise as a part of treatment for
 gestational diabetes mellitus.
- Gestational diabetes mellitus is not of itself an indication for cesarean delivery or for delivery before 38 completed weeks of gestation. Prolongation of gestation past 38 weeks increases the risk of fetal macrosomia without reducing cesarean rates, so that delivery during the 38th week is recommended unless obstetric considerations dictate otherwise.

 Breast-feeding, as always, should be encouraged in women with gestational diabetes mellitus.

Long-term Therapeutic Considerations

- Reclassification of maternal glycemic status should be performed at least 6
 weeks after delivery and according to the guidelines of the "Report of the
 Expert Committee on the Diagnosis and Classification of Diabetes Mellitus."
 See Table 3 in the original guideline document for diagnostic criteria.
- If glucose levels are normal postpartum, reassessment of glycemia should be undertaken at a minimum of 3-year intervals.
- Women with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) in the postpartum period should be tested for diabetes annually; these patients should receive intensive medical nutrition therapy and should be placed on an individualized exercise program because of their very high risk for development of diabetes.
- All patients with prior gestational diabetes mellitus should be educated regarding lifestyle modifications that lessen insulin resistance, including maintenance of normal body weight through medical nutrition therapy and physical activity. Medications that worsen insulin resistance (e.g., glucocorticoids, nicotinic acid) should be avoided if possible. Patients should be advised to seek medical attention if they develop symptoms suggestive of hyperglycemia. Education should also include the need for family planning to assure optimal glycemic regulation from the start of any subsequent pregnancy. Low-dose estrogen-progestogen oral contraceptives may be used in women with prior histories of gestational diabetes mellitus, as long as no medical contraindications exist.
- Offspring of women with gestational diabetes mellitus should be followed closely for the development of obesity and/or abnormalities of glucose tolerance.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on the evidence reviewed in the following publications: Report of the expert committee on the diagnosis and classification of diabetes mellitus. Diabetes Care 1998; 21(Suppl 1): S5-S19; and the Proceedings of the 4th International Workshop-Conference on Gestational Diabetes Mellitus. Diabetes Care 1998; 21(Suppl 2): B1-B167.

POTENTIAL BENEFITS

- Decreased maternal glucose levels. Programs of moderate physical exercise have been shown to lower maternal glucose concentrations in women with gestational diabetes mellitus. Restriction of carbohydrates to 35 to 40% of calories has been shown to decrease maternal glucose levels. For obese women (body mass index >30), a 30 to 33% calorie restriction (to ~25 kcal/kg actual weight per day) has been shown to reduce hyperglycemia and plasma triglycerides with no increase in ketonuria.
- Reduction in fetal morbidities. Insulin is the pharmacologic therapy that has
 most consistently been shown to reduce fetal morbidities when added to
 medical nutrition therapy. Restriction of carbohydrates to 35 to 40% of
 calories has been shown to improve maternal and fetal outcomes.
- Improved maternal outcomes. Restriction of carbohydrates to 35 to 40% of calories has been shown to improve maternal outcomes.

POTENTIAL HARMS

None stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- 75-g glucose load is not as well validated for detection of at-risk infants or mothers as the 100-g oral glucose tolerance test.
- The use of insulin analogs has not been adequately tested in gestational diabetes mellitus.
- Oral glucose-lowering agents have generally not been recommended during pregnancy. However, one randomized, unblinded clinical trial compared the use of insulin and glyburide in women with gestational diabetes mellitus who were not able to meet glycemic goals on medical nutrition therapy. Treatment with either agent resulted in similar perinatal outcomes. However, glyburide is not Food and Drug Administration (FDA)-approved for the treatment of gestational diabetes and further studies are needed in a larger patient population to establish its safety.
- The impact of exercise on neonatal complications awaits rigorous clinical trials.
- For women treated with insulin, limited evidence indicates that postprandial monitoring is superior to preprandial monitoring. However, the success of either approach depends on the glycemic targets that are set and achieved.
- Evidence is only one component of decision-making. Clinicians care for
 patients, not populations; guidelines must always be interpreted with the
 needs of the individual patient in mind. Individual circumstances such as
 comorbid and coexisting diseases, age, education, disability, and above all,
 patient's values and preferences must also be considered and may lead to
 different treatment targets and strategies. Also, conventional evidence
 hierarchies such as the one adapted by the American Diabetes Association
 may miss some nuances that are important in diabetes care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Gestational diabetes mellitus. Diabetes Care 2004 Jan; 27(Suppl 1): S88-90. [5 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1986 (revised 2000; republished 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

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GUI DELI NE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline was originally approved in 1986. The most recent review/revision was completed in 2000.

American Diabetes Association (ADA) position statements are reissued annually.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Diabetes Association (ADA) Web</u> site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 1998; 21(Suppl 1): S5-S19.
- Proceedings of the 4th International Workshop-Conference on Gestational Diabetes Mellitus. Diabetes Care 1998; 21(Suppl 2): B1-B167.

Print copies: Available from the American Diabetes Association (ADA), 1600 Duke Street, Alexandria, VA 22314.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. The summary was updated by ECRI on January 29, 2002, April 21, 2003, and March 24, 2004.

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